



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/661,804	09/12/2003	Gerold Schuler	1430/16	8361

25297 7590 03/15/2007
JENKINS, WILSON, TAYLOR & HUNT, P. A.
3100 TOWER BLVD
SUITE 1200
DURHAM, NC 27707

EXAMINER

QIAN, CELINE X

ART UNIT	PAPER NUMBER
----------	--------------

1636

MAIL DATE	DELIVERY MODE
-----------	---------------

03/15/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action
Before the Filing of an Appeal Brief**

Application No.

10/661,804

Applicant(s)

SCHULER ET AL.

Examiner

Celine X. Qian Ph.D.

Art Unit

1636

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 07 February 2007 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
(b) ☐ They raise the issue of new matter (see NOTE below);
(c) ☒ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
The status of the claim(s) is (or will be) as follows:
Claim(s) allowed: _____.
Claim(s) objected to: _____.
Claim(s) rejected: 12 and 24-32.
Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:
See Continuation Sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____.
13. ☐ Other: _____.

Celine X Qian Ph.D.
Examiner
Art Unit: 1636

Continuation of 3. NOTE: the proposed amendment does not overcome the art rejection of the record (see reasons set forth below), therefore, it does not place the application in better form for appeal by materially reducing and simplifying the issues for appeal. As such, it will not be entered.

Continuation of 11. does NOT place the application in condition for allowance because: the arguments are not persuasive. Applicants argue that Jonuleit et al. teach directly contacting human blood with CD24, CD25 and/or CTLA-4 specific antibodies as claimed because the cells are first removed by CD4 antibody and stimulated with DC in vitro, then contacted with CD25 antibody, thus the cell population disclosed in Jonuleit is non-naturally occurring. Applicants further assert that the cell produced by Jonuleit are not CD4+CD25+ regulatory cells. This argument is not persuasive because the claimed method uses open claim language with regard to the number of the steps and thus encompasses embodiments where the blood cells may be cultured or processed (i.e. stimulated) before directly contacted with CD4 and CD25 antibody. With regard to the cells being non-naturally occurring, Applicants are reminded that there is no evidence that such cells do not occur in nature because said cells are obtained from human blood, and stimulation with iDC can occur both in vitro and in vivo. The specification does not teach what properties of the claimed cells are different from the property of the cells taught in Jonuleit, and the claims do not recite any properties that are different from those cells. Absent evidence from the contrary, the Tr1 like cells taught by Jonuleit, though have a different name, is considered as regulatory CD4+CD25+ regulatory T cells based on the disclosed property. Similarly, Applicants argue that Horwitz et al. teach pretreatment and induction of the cells isolated from blood to generate CD4+CD25+ regulatory cells, thus the resultant cells are not naturally occurring. This argument is not persuasive for same reason as set above. The arguments directed to 103 rejection are not persuasive for same reason as set forth above. Therefore, the rejection is maintained.

CELINE QIAN, PH.D.
PRIMARY EXAMINER

